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Elaine C. Stracker



PATENT
Attorney's Docket No.: 00064.01R

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hale et al.
Serial No.: 10/719,763
Filed: 11/20/2003
Title ACUTE TREATMENT OF HEADACHE WITH PHENOTHIAZINE
ANTIPSYCHOTICS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their continuing duty of disclosure under 37 CFR §§ 1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

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Respectfully submitted,

Date: SEP. 24 2004



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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/719,763	
	Filing Date	11/20/2003	
	First Named Inventor	Ron L. Hale	
	Art Unit	Not yet known	
	Examiner Name	To be assigned	
Total Number of Pages in This Submission		Attorney Docket Number	00064.01R

ENCLOSURES (check all that apply)		
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Info. Discl. Statemetn (2 pp.) Form 1449 (3 copies, 4 pages each) Copy of 66 references Return Postcard		

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Firm or Individual name	ALEXZA MDC, 1001 East Meadow Circle, Palo Alto, CA 94303 Elaine C. Stracker, Ph.D., J.D. Telephone (650)-687-3905 Customer Number 37485
Signature	
Date	SEP. 24 2004

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Form PTO-1449

Docket Number: 00064.01R

Application Number: 10/719,763

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

(Use several sheets if necessary)

Applicant:

HALE et al.

Filing Date: 11/20/2003

Group Art Unit: Not Yet Known

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	09/01/1959	2,902,484	Horclois et al.			
	2.	11/15/1994	5,364,838	Rubsamen			
	3.	07/11/1995	5,431,167	Savord			
	4.	03/23/1999	5,884,620	Gonda et al.			
	5.	07/27/1999	5,929,070	Shannon et al.			
	6.	08/24/1999	5,941,240	Gonda et al.			
	7.	08/31/1999	5,945,416	Shannon et al.			
	8.	01/02/2001	6,167,880	Gonda et al.			
	9.	06/26/2001	6,250,298	Gonda et al.			
	10.	07/10/2001	6,258,807	Helton et al.			
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	12.	04/23/2002	6,376,550	Raber et al.			
	13.	06/25/2002	6,408,854	Gonda et al.			
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	15.	09/03/2002	6,444,665	Helton et al.			
	16.	10/08/2002	6,461,591	Keller et al.			
	17.	02/04/2003	6,514,482	Bartus et al.			
	18.	05/16/2002	US 2002/0058009	Bartus et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	19.	05/11/1994	WO 94/09842	WIPO			
	20.	12/20/2001	WO 01/095903	WIPO			

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Applicant:

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	21.	03/28/2002	WO 02/024158	WIPO			
	22.	11/28/2002	WO 02/094236	WIPO			

RELATED ALEXZA MOLECULAR DELIVERY CORPORATION PATENT DOCUMENTS

	23.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
	24.	07/01/2004	US 2004/0126329	Rabinowitz et al.			
	25.	01/27/2004	10/766,647	Rabinowitz et al.			
	26.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
	27.	08/12/2004	US 2004/0156791	Rabinowitz et al.			
	28.	01/28/2004	10/767,115	Rabinowitz et al.			
	29.	01/30/2003	US 2003/0021754	Rabinowitz et al.			
	30.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
	31.	01/29/2004	10/768,220	Rabinowitz et al.			
	32.	08/04/2003	10/633,877	Hale et al.			
	33.	08/04/2003	10/633,876	Hale et al.			
	34.	5/27/2004	US 2004/0102434	Hale et al.			
	35.	05/27/2004	US 2004/0099269	Hale et al.			

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(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	36.	Bowden, et al. (1988) "The Effect of Trifluoperazine on Bronchial Responsiveness in Asthma" <i>Clinical and Experimental Pharmacology & Physiology</i> 15: 457-463.
	37.	Collins, et al. (2001) "Intravenous Administration of Prochlorperazine by 15-Minute Infusion Versus 2-Minute Bolus Does Not Affect the Incidence of Akathisia: A prospective Randomized, Controlled Trial" <i>Annals of Emergency Medicine</i> 38:5 491-496.
	38.	Kabbouche, et al. (2001) "Tolerability and Effectiveness of Prochlorperazine for Intractable Migraine in Children" <i>Pediatrics</i> Vol. 107 No. 4.
	39.	Ginder et al. (2000) "A Prospective Study of I.V. Magnesium and I.V. Prochlorperazine in the Treatment of Headaches" <i>The Journal of Emergency Medicine</i> : Vol. 18 No. 3: 311-315.

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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 00064.01R	Application Number: 10/719,763
	Applicant: HALE et al.	
	Filing Date: 11/20/2003	Group Art Unit: Not Yet Known

40.	Sharma, et al. (2002) "Efficacy and Tolerability of Prochlorperazine Buccal Tablets in Treatment of Acute Migraine" <i>Headache</i> : 42: 896-932.
41.	Thomas, et al. (1994) "Intravenous Versus Rectal Prochlorperazine in the Treatment of Benign Vascular or Tension Headache: A Randomized, Prospective, Double-Blind Trial" <i>Annals of Emergency Medicine</i> 24:5 923-927.
42.	Seim, et al. (1998) "Intravenous Ketorolac vs. Intravenous Prochlorperazine for the Treatment of Migraine Headaches" <i>Academic Emergency Medicine</i> Vol. 5, No. 6.
43.	Coppola, et al. (1995) "Randomized, Placebo-Controlled Evaluation of Prochlorperazine Versus Metoclopramide for Emergency Department Treatment of Migraine Headache" <i>Annals of Emergency Medicine</i> Vol 25 No. 5.
44.	Miller-Gibson et al. (2002) "273 Intravenous sodium valproate versus prochlorperazine for the emergency department treatment of acute migraine headache." <i>Annals of Emergency Medicine</i> Vol 40 No. 4.
45.	Miner et al. (2001) "Droperidol vs. Prochlorperazine for Benign Headaches in the Emergency Department." <i>Academic Emergency Medicine</i> Vol. 8 No. 9.
46.	Saada, Hanna A. (1992) "Abortive Headache Therapy in the Office with Intravenous Dihydroergotamine Plus Prochlorperazine." <i>Headache</i> 32:143-146.
47.	Saada, Hanna A. (1994) "Abortive Migraine Therapy in the Office with Dexamethasone and Prochlorperazine." <i>Headache</i> 34:366-370.
48.	Lu et al. (2000) "Repetitive Intravenous Prochlorperazine Treatment of Patients with Refractory Chronic Daily Headache." <i>Headache</i> Vol 40:724-729.
49.	Silberstein et al. (2002) "Olanzapine in the Treatment of Refractory Migraine and Chronic Daily Headache" <i>Headache</i> Vol. 42:515-518.
50.	Rozen et al. (2001) "Olanzapine as an Abortive Agent for Cluster Headache." <i>Headache</i> Vol. 41:813-816.
51.	Lane et al. (1989) "Comparative Efficacy of Chlorpromazine and Meperidine with Dimenhydrinate in Migraine Headache." Vol. 18:4.
52.	Shrestha et al. (1996) "Ketorolac vs Chlorpromazine in the Treatment of Acute Migraine Without Aura." <i>Arch. Intern. Med.</i> Vol. 156:1725-1728.
53.	Bigal, et al. (2002) "Intravenous Chlorpromazine in the Emergency Department Treatment of Migraines: A Randomized Controlled Trial." <i>The Journal of Emergency Medicine</i> Vol. 23, No. 2: 141-148.
54.	Kelly, Anne-Maree (2000) "Migraine: Pharmacotherapy in the Emergency Department" <i>WJM</i> Vol. 173: 189-193.
55.	Dahloef, et al. (1998) "Pathophysiology and pharmacology of migraine. Is there a place for antiemetics in future treatment strategies" <i>Cephalalgia</i> Vol. 18: 594-604.

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56.	Mascia et al. (1998) "Dopamine and migraine: a review of pharmacological, biochemical, neurophysiological, and therapeutic data" <i>Cephalgia</i> Vol. 18:174-182.
57.	Peroutka, Stephen J. (1997) "Dopamine and migraine" <i>Neurology</i> 49:650-656.
58.	Caviness, Verne S. (May, 1980) "Cluster Headache: Response to Chlorpromazine" <i>Headache</i> 128-131.
59.	Blanda et al. (2001) "Intranasal Lidocaine for the Treatment of Migraine Headache: A Randomized, Controlled Trial" <i>Academic Emergency Medicine</i> Vol. 8:337-342.
60.	Tanen et al. (2003) "Intravenous Sodium Valproate Versus Prochlorperazine for the Emergency Department Treatment of Acute Migraine Headaches: A Prospective, Randomized, Double-Blind Trial" <i>Annals of Emergency Medicine</i> Vol. 41:847-853.
61.	Kabbouche et al. (2001) "Tolerability and Effectiveness of Prochlorperazine for Intractable Migraine in Children" <i>Pediatrics</i> Vol. 107 No. 4.
62.	Hagenbach, Charles "Prochlorperazine in the Prophylaxis of Migraine" <u>General Practitioners' Forum</u> Pages 503-506.
63.	Jones et al. (1996) "Intramuscular Prochlorperazine Versus Metoclopramide as Single-Agent Therapy for the Treatment of Acute Migraine Headache" <i>American Journal of Emergency Medicine</i> Vol. 14 No. 3.
64.	Jones et al. (1995) Abstract: "Intramuscular Prochlorperazine Versus Metoclopramide for the Treatment of Acute Migraine Headache" <i>Annals of Emergency Medicine</i> Vol. 25 No. 1: 154.
65.	Donohue et al. (1995) Abstract: "Prochlorperazine Versus Sumatriptan for Emergency Department Therapy of Migraine Headache" <i>Annals of Emergency Medicine</i> Vol. 25 No. 1: 154.
66.	Coppola et al. (1995) Abstract: "A Prospective, Double-blind Evaluation of Prochlorperazine vs. Sumatriptan for the Emergency Department Treatment of Migraine Headache." <i>Annual Meeting Abstracts</i> Vol. 2 No. 5: 367-368.

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